

**Science Advisory Board (SAB)/Board of Scientific Counselors (BOSC) Draft Report (11/27/12) to Assist
Meeting Deliberations -- Do Not Cite or Quote --**

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EPA-SAB-12-001

The Honorable Lisa P. Jackson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Subject: Office of Research and Development (ORD) Implementation of its Strategic Research Plans:
A Joint Report of the Science Advisory Board (SAB) and ORD Board of Scientific Councilors (BOSC)

Dear Administrator Jackson:

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NOTICE

This report has been written as part of the activities of the EPA Science Advisory Board (SAB) and the Office of Research and Development (ORD) Board of Scientific Counselors (BOSC). The SAB is a public advisory group providing extramural scientific information and advice to the Administrator and other officials of the Environmental Protection Agency. The SAB is structured to provide balanced, expert assessment of scientific matters related to problems facing the agency. The BOSC is also a balanced, expert public advisory group. It provides extramural scientific information and advice to the ORD Assistant Administrator. This report has not been reviewed for approval by the agency, and, hence, the contents of this report do not necessarily represent the views and policies of the Environmental Protection Agency or other agencies in the Executive Branch of the Federal government. Mention of trade names of commercial products does not constitute a recommendation for use. Reports of the SAB are posted on the EPA website at <http://www.epa.gov/sab>, and reports of the BOSC are posted on the EPA website at <http://www.epa.gov/osp/bosc>.

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**U.S. Environmental Protection Agency
Science Advisory Board
FY 2012**

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Acronyms and Abbreviations

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1. EXECUTIVE SUMMARY

(use "Heading 1" Style)

1.1. Heading Level 2

1.1.1. Heading Level 3

Heading Level 4

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2. BACKGROUND AND CHARGE

In 2012, the Office of Research and Development (ORD) developed strategic research action plans for its six research areas and an overview plan after receiving advice from the SAB and BOSC in 2011 [U.S. EPA SAB 2012). The restructured research programs comprise six program areas: Air, Climate, and Energy; Safe and Sustainable Water Resources; Sustainable and Healthy Communities; Chemical Safety for Sustainability; Human Health Risk Assessment; and Homeland Security. ORD requested additional advice in 2012 on ORD's research implementation plans, efforts to strengthen program integration; and efforts to strengthen and measure innovation.

The SAB and the BOSC held a public meeting on July 10-11, 2012, to discuss the strategic research action plans, information about five integration topics presented by ORD (Nitrogen; Global Climate Change; Children's Health/Environmental Justice; Applying new chemical assessment approaches in human health risk assessment; Endocrine-mediated Dose-Response) and ORD efforts to encourage innovation. SAB and BOSC also held a public teleconference on September xx, 2012 to discuss a draft of this report.

ORD requested the SAB and BOSC address: 1) three charge questions related to first year progress, sustainability, and balancing immediate needs and emerging issues for each of the major research areas 2) specific charge questions for each program area; and 3) general questions pertaining to integration and innovation in ORD programs. Appendix A provides ORD's charge to the SAB and BOSC.

Section 3 provides an overview of major findings and recommendations related to the charge questions below.

1. First year progress. How are the ORD research programs progressing in the first year of implementation? Are the research activities planned for FY 13 and future years appropriate for answering the science questions in the Strategic Research Action Plan?
2. Sustainability. How are ORD programs contributing to sustainability through their research plans and activities? What advice does the SAB and BOSC have for each research program about advancing sustainability in future research?
3. Balancing immediate program needs and emerging issues. As we consider science for the future, while budgets continue to shrink, how should ORD balance its commitments in the Strategic Research Action Plan with the need to advance science on emerging issues?
4. Integration. Based on the presentation of five integrated topics, what advice can the SAB and BOSC provide to help ORD succeed in integrating research across the ORD programs? How can different approaches to integration help us achieve our research goals?

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5. How can ORD's initial innovation activities be improved to ensure continued and long term benefits for EPA? Are there useful experiences and lessons from other research organizations about managing innovation? What guidance can the SAB and BOSC provide for ORD in developing metrics that would be most effective in assessing the success of our innovation efforts?

Section 4 of this report provides more program-specific detail and responses to the specific charge questions for each program area.

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3. OVERVIEW OF MAJOR FINDINGS AND RECOMMENDATIONS

3.1. Introduction

3.1.1. Heading Level 3

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3.2. First year progress

*How are the ORD research programs progressing in the first year of implementation? Are the
research activities planned for FY 13 and future years appropriate for answering the science
questions in the Strategic Research Action Plan?*

3.2.1. Response

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3.2.2. Major recommendations

3.3. Sustainability

*How are ORD programs contributing to sustainability through their research plans and activities?
What advice does the SAB and BOSC have for each research program about advancing
sustainability in future research?*

The SAB and BOSC suggest that the Plan incorporate ecological health as well as human health into the
definition of sustainability, and that each research program define what sustainability means within the
context of that program.

Commented [E1]: From CSS

3.3.1. Response

SAB/BOSC commends EPA for establishing a single definition for sustainability across ORD, and
recommends that each program define more specifically what sustainability means within the program
context.

3.3.2. Major recommendations

- SAB/BOSC recommends that each program define more specifically what sustainability means
within the program context.

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3.4. Balancing immediate program needs and emerging issues.

As we consider science for the future, while budgets continue to shrink, how should ORD balance its commitments in the Strategic Research Action Plan with the need to advance science on emerging issues?.

3.4.1. Response

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3.4.2. Major recommendations

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3.5. Integration

Based on the presentation of five integrated topics, what advice can the SAB and BOSC provide to help ORD succeed in integrating research across the ORD programs? How can different approaches to integration help us achieve our research goals?

3.5.1. Response

SAB/BOSC commends EPA for significantly improving how it integrates research across its programs. EPA ORD has made rapid and significant progress.

EPA could facilitate progress in the integrated research topics if it developed individual “roadmaps” with goals and an outline of paths to those goals for each of the integrated research topics, similar to the roadmaps being developed for EPA’s integrated nitrogen and climate research topics. In addition, SAB/BOSC recommends that EPA develop a graphical framework for each integrated research topic that identifies the various participating EPA programs and external agencies and groups, the distribution of responsibilities, and how the various participants are linked to each other and to the research effort. This framework should clearly identify the EPA program that would take the lead in the integrated research effort, and resources should be managed accordingly.

SAB/BOSC notes that some areas of research integration have obvious rationale, such as integration of chemical safety with air and water research, but the need for integration across other areas requires careful consideration. The five integration topics selected by EPA are good ones, and probably sufficient for now. Integration of research should be initiated when there is a compelling topic and it makes sense to do so, recognizing that not all topics will require assistance from all program areas.

3.5.2. Major recommendations

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Commented [E3]: From SSWR

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- EPA should develop individual “roadmaps” with goals and an outline of paths to those goals for each of the integrated research topics, similar to the roadmaps being developed for EPA’s integrated nitrogen and climate research topics.
- EPA should develop a graphical framework for each integrated research topic that identifies and discusses the responsibilities and relationships of the various participating EPA programs and external agencies and groups.
- EPA should enhance its internal and external communication between research programs and provide more opportunities for formal exchange of research information.

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3.6. Innovation

How can ORD’s initial innovation activities be improved to ensure continued and long term benefits for EPA? Are there useful experiences and lessons from other research organizations about managing innovation? What guidance can the SAB and BOSC provide for ORD in developing metrics that would be most effective in assessing the success of our innovation efforts?

3.6.1. Response

- a) How can ORD’s initial innovation activities be improved to ensure continued and long term benefits for EPA?

ORD should be commended on its efforts to foster innovation. The success of such an approach is strongly dependent on the leader and the continued fostering of the innovative culture and the first year results. The initiation of the PIP program along with the large response for the call for proposals and some preliminary results indicates a very good start. However, it is important to EPA to make sure that all proposed innovation activities are tied to the agency mission. Innovative activities and support of those activities should be prioritized to reflect EPA’s most pressing needs. What are those Grand Challenges that, if addressed in an innovative way, will lead to a quantum leap in the way EPA performs its duties? For example, imagine the value of having output of IRIS increase by an order of magnitude. An overarching Grand Challenge for ORD is to innovate in a contracting fiscal environment and in the “public sector which is not designed to foster creativity” (Peter Preuss statement on the challenges of innovation). Time management needs to be considered, as too much time spent on writing proposals may produce a deficiency in the researcher pursuing regular work activities.

Approaches to innovation beyond the PIP program that have been mentioned by Peter Preuss as well as members of the BOSC and SAB include:

- X-prize engages the public
- Open innovation/Crowd sourcing (utilize communities and students)
- Looking to young investigators for fresh ideas
- Skunkworks approach—Take a small number of innovative thinkers and encourage wild ideas and experimentation while accepting that there will be failures but some successes. These investigators should be allowed to operate with minimal reporting requirements and enhanced programmatic flexibility. Innovative thinkers from very different fields would work together to

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increase the potential for innovation as each brings a completely different set of ideas to the table.

If the objective of innovation in ORD is to make it an overarching theme at ORD there are challenges that still remain:

- Differentiating between innovation and evolutionary research approaches
- Keeping up the exceptional innovative ideas and energy in the proposal submission over time
- Tracking the change in the ORD culture towards more innovation (metrics?)

b) Are there useful experiences and lessons from other research organizations about managing innovation?

Because the SAB and BOSC members are, on the whole, inherently research oriented, a number of references were provided both for experiences/lessons learned as well as scientifically assessed metrics. Since there is a depth of knowledge and experience in the SAB and BOSC, it is suggested that the SAB and BOSC provide ORD with a bibliography of lessons learned reports and metrics generation (or we can add them here? We should discuss. There were a number of good suggested metrics references as well as peer reviewed articles discussing fostering innovation).

c) What guidance can the SAB and BOSC provide for ORD in developing metrics that would be most effective in assessing the success of our innovation efforts?

The development of metrics seems to be the Grand Challenge in itself. There were wide ranging thoughts on this topic. Some members suggest that metrics are not important rather the 'just do it' should be the operative direction. Other members suggested that business innovation metrics should be avoided; others suggested metrics that are common for academic decisions on innovation (number of publications, citations, etc.) would be acceptable and provided technical research on the subject. Realizing that innovation and in-house government research may often be viewed as mutually exclusive, ORD may be better served by having a focused workshop on metric development for innovation that would result in a set of metrics that represents a reasonable fit with the ORD mission and desire for innovation. Additionally, there may be different metrics for different aspects of a proposed innovative project.

- 1) Does the proposal fit a mission area?
- 2) Is it innovative or just evolutionary?
- 3) Are there phases in the proposal (skunkworks type approach)? A) idea development, B) proof of concept, C) innovation development. If so there may be metrics needed for each phase in order to justify funding from one phase to the next.
- 4) What is the transition plan (what happens after the project is successful. Who is the customer? EPA? If there was no buyer for the technology, does it have value to the agency and worth pursuing?

Another metric that needs to be seriously considered is an award system which should, at least, align with the desired behavioral changes in moving the ORD culture to one of innovation

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.....
SAB/BOSC commends EPA ORD for its significant strides in identifying and encouraging innovation across EPA.

SAB/BOSC recommends that EPA identify and focus its metrics on the goals of EPA's organizations and their specific projects, rather than on conventional business performance metrics, when assessing potential innovation projects and impacts of innovation projects. SAB/BOSC notes that much of the innovation program is currently focused on technological innovations ("widgets"). Often the most inventive solutions to environmental problems involve new ways of doing things, through new organizational forms or ways of working together, rather than new technologies. In addition, existing technologies can become part of solutions that involve changing the way people use technologies (which some call "sociotechnical systems"). The program should provide as much encouragement for social and sociotechnical innovations as for purely technological ones. A useful reference for further information on this topic is the National Academy of Engineering's "Industrial Environmental Performance Metrics: Challenges and Opportunities" (1999).

SAB/BOSC encourages EPA to consider multiple benefits when assessing innovations (e.g., resource recovery).

EPA should also use competitions or targeted outreach efforts to identify examples of successful innovation projects implemented in communities and utilities across the country. SAB/BOSC notes that other countries (e.g., India, Brazil and Nigeria) have found success in identifying solutions to their environmental problems by soliciting innovative approaches directly from community groups experiencing the negative impacts for which innovative solutions are sought.

Commented [E6]: From SSWR

We applaud the current innovation program and support its further growth. It appears that this program is already becoming ingrained within the culture of ORD, and is fostering more creativity and is encouraging smart risk-taking. The program also appears to yield the double benefit of enhancing integration, as many of the innovation projects are characterized by cross-fertilization across disciplines.

Although the committee supports ORD's efforts to develop innovative ideas from across ORD, it was recognized that some individuals are more consistently innovative than others (e.g., repeat PIP award winners). We encourage additional efforts to identify and leverage the top innovators via mentoring of others and/or assembling the top innovators in small teams to promote further breakthroughs. The Agency should naturally ensure that innovation is not done for the sake of innovation, but that its products are applied, leveraged broadly, and built upon.

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Among the issues raised in regards to innovation were:

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- Provide more information on the guiding principles that govern how PIP grants are awarded and how questions for challenges are chosen
- Future research calls should be targeted to specific science questions in ORD programs
- There was concern expressed about the large number of proposals submitted and the low number of proposals funded. Low success rates represent a huge investment of staff time that do not lead to on-going efforts and the possibility that staff morale could decline.

Commented [E8]: From SHC

3.6.2. Major recommendations

- When assessing potential innovation projects and impacts of innovation projects, EPA should consider multiple benefits of such projects, and identify and focus its metrics on the goals of EPA's organizations and their specific projects rather than on conventional business performance metrics.
- EPA should use competitions or targeted outreach efforts to identify examples of successful innovation projects implemented in communities and utilities across the country.

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4. PROGRAM-SPECIFIC RESPONSES

4.1. Air, Climate and Energy

4.1.1. Overview questions

First year progress

*How are the ORD research programs progressing in the first year of implementation? Are the
research activities planned for FY 13 and future years appropriate for answering the science
questions in the Strategic Research Action Plan?*

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Sustainability

*How are ORD programs contributing to sustainability through their research plans and activities?
What advice does the SAB and BOSC have for each research program about advancing
sustainability in future research?*

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Heading Level

Balancing immediate program needs and emerging issues.

*As we consider science for the future, while budgets continue to shrink, how should ORD balance its
commitments in the Strategic Research Action Plan with the need to advance science on emerging
issues?.*

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Integration

*Based on the presentation of five integrated topics, what advice can the SAB and BOSC provide to
help ORD succeed in integrating research across the ORD programs? How can different
approaches to integration help us achieve our research goals?.*

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Innovation

*How can ORD's initial innovation activities be improved to ensure continued and long term benefits
for EPA? Are there useful experiences and lessons from other research organizations about
managing innovation? What guidance can the SAB and BOSC provide for ORD in developing
metrics that would be most effective in assessing the success of our innovation efforts?*

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4.1.2. Program –specific questions

First program specific question title

Program Specific Question

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Second Program Specific Question Title

Text of Program-specific question

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4.2. Chemical Safety for Sustainability

The Chemical Safety for Sustainability (CSS) program is intended to provide critical research providing the scientific foundations supporting Agency programs to ensure safety in the design, manufacture and use of existing and future chemicals. This program is ambitious and bold, and appropriately so as the entire field of chemical safety assessment is in the midst of a radical transformation needed to meet the changing needs of today's world. The demands being placed upon the Agency's safety assessment programs are far more challenging than they have ever been in the past, and are prompting questions such as: how to design and produce safer chemicals, how chemicals and their byproducts move through the environment, what are the sources of chemical exposure, how might chemicals and other exposures alter cellular and molecular control pathways leading to adverse outcomes, and what contribution does chemical exposure make to the overall disease burden in humans (including susceptible subpopulations) and the environment.

Clearly, transforming safety assessment to meet these challenges is major undertaking that will take many years to fully accomplish. However, the journey is now underway and it is imperative that it succeed. At stake are not only major opportunities to improve public and environmental health, but to do so in ways that are swift, cost effective and supportive of our nation's innovation engine (e.g., new, more sustainable products). Overall, the SAB and BOSC voice strong support and endorsement of the Strategic Research Action Plan for the CSS program. This report also offers a number of specific suggestions for improving upon this already strong plan.

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4.2.1. Overview questions

First year progress

How are the ORD research programs progressing in the first year of implementation? Are the research activities planned for FY 13 and future years appropriate for answering the science questions in the Strategic Research Action Plan?

The SAB and BOSC are impressed with the progress made in the first year of the CSS program's implementation, and even went so far to proclaim that it "exceeded expectations" in some instances. This progress was primarily related to creating a new, highly integrated management infrastructure that is radically different from the previous structure. This was no small task to create, and will also take much work to maintain, but it is fundamental and necessary to achieving the desired level integration along multiple axes and to accomplish the ambitious goals articulated in the Plan. It is noted that the scope of the Plan goes beyond the traditional confines of risk assessment by also integrating certain aspects of risk management in its design. Examples of this include the application of high throughput predictive toxicology data and computational approaches to inform "Green Chemical" design, as well as the consideration of product life cycle in the development of new approaches to safety assessment. While not a research product in and of itself, the Strategic Plan should be considered a major accomplishment in its own right.

Given that this is just the first year of a multi-year research program it is too early to judge success in terms of specific research deliverables, but certainly early progress is very encouraging. Approximately 75% of the CSS research program portfolio deals with the development of new tools for safety assessment. Assuming that these new tools are found useful by users and their outputs accepted by stakeholders (more on this later), the impact from the CSS is expected to be quite high and readily quantifiable.

In regard to the appropriateness of the research activities planned for FY 13 and future years for answering the science questions in the Strategic Research Action Plan, the SAB and BOSC consider the CSS research plan to be comprehensive. Reviewers found that it contained all of the key elements needed to answer the science questions in the Strategic Research Action Plan. However, several particular elements warrant further discussion, specifically exposure, cumulative risk and ecosystems.

The SAB and BOSC are pleased that exposure research has a greater presence in the plan than in any previous plan. While it was agreed that exposure is embedded throughout most, if not all, aspects of the plan, additional focus needs to be placed on the refinement and validation of proximal and consumer (also referred to by some as "near field") exposure models. Several reviewers suggested that exposure be specifically highlighted as a theme of its own. If such were the case, exposure might get even more attention and resources; something which is strongly encouraged. It should be noted that "exposure" as referred to here includes both external exposure and internal exposure (i.e., toxicokinetics), and applies to humans, wildlife and ecosystems. While the SAB and BOSC are aware of legal/policy constraints precluding the conduct of human exposure studies by EPA, it is possible to conduct such studies in a safe and ethical manner as demonstrated by other research organizations. Such studies would bring

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tremendous value in the assessment of chemical safety and will be important to put the results from the *in vitro* high-throughput screening studies into the appropriate context.

Cumulative risk. One example of the benefits of integration relates to the potential value of systems models and toxicity pathways data for informing chemical grouping schemes based upon common mode of action. Another example of which we are supportive relates to the inclusion of both chemical and non-chemical stressors (e.g., socioeconomic factors).

Ecosystems. It is recommended that the CSS Plan more clearly state the emphasis on ecosystems research.

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Sustainability

*How are ORD programs contributing to sustainability through their research plans and activities?
What advice does the SAB and BOSC have for each research program about advancing sustainability in future research?*

In the case of the CSS program, contributions to sustainability are many and include, but are not limited to, the following:

- The use of high throughput, predictive toxicology approaches to inform Green Chemical Design, thus supporting the production of newer chemicals with more sustainable characteristics (e.g., reduced intrinsic hazards, less energy-consumptive, more biodegradable);
- New assessment approaches that consider product life cycles (cradle to grave) to enable protection against not only the chemical itself, but its environmental degradation products and unique types of exposures that might occur during different phases of the product's life cycle;
- Research to understand life stage variability to help enhance protection of sensitive age-specific subpopulations;
- Development of more holistic ecosystems-based approaches to ensure more integrated, "one environment" safety assessments
- The use of systems approaches to transform chemical safety assessment from a series of isolated tests to a much more integrated and quite likely, more efficient and cost-effective enterprise.
- "Extrapolation" approaches to link different levels of biological organization

As mentioned in prior BOSC comments, it is highly recommended that specific metrics be created to measure the contributions to sustainability derived from the CSS program.

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It is recommended that when describing CSS research and its deliverables that care is taken to also demonstrate how the research impacts upon end users (e.g., risk managers, policy makers) and how it brings value for informing decisions.

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Balancing immediate program needs and emerging issues.

As we consider science for the future, while budgets continue to shrink, how should ORD balance its commitments in the Strategic Research Action Plan with the need to advance science on emerging issues?.

ORD's transition to a more integrated structure is requiring a considerable increase in staff re-training and an enhanced culture of continual learning, which in turn is expected to result in a more diversified suite of skill sets across ORD. Integration also creates more efficient networks of expertise that can be more rapidly and effectively tapped when new issues arise. Integration also is promoting cross-fertilization of ideas and skill sets. All of these will enhance ORD's capacity to adapt to critical emerging issues even in a fiscally lean environment. We applaud EPA's ongoing budget scenario planning exercise and their recognition that doing a smaller number of things well is much better than dabbling in many areas.

Integration

Based on the presentation of five integrated topics, what advice can the SAB and BOSC provide to help ORD succeed in integrating research across the ORD programs? How can different approaches to integration help us achieve our research goals?.

To further promote integration across ORD programs, the following are suggested:

- 1) Increasingly utilize the Adverse Outcome Pathway (AOP) concept as it is an inherently integrative process in itself. One example is the Duluth lab's project on AOPs in which the vitellogenin pathway was linked all the way to population level changes.
- 2) Whenever possible, try to directly link ORD science to end users, such as regulators at regional office level.
- 3) Highlighting key examples of successful integration as done in the opening day's presentations also will be helpful, particularly if the key elements of integration are emphasized. For example, in the Children's Health program example, the integration of both chemical and non-chemical stressors was emphasized.
- 4) With respect to the Nitrogen program specifically, this could be further integrated by incorporating community ground water exposure data.

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4.2.2. Program –specific questions

Endocrine disrupting chemicals, nanotechnology, and computational toxicology

Is the CSS program well positioned to support EPA needs in the three key areas of endocrine disrupting chemicals, nanotechnology, and computational toxicology research?

EPA is not only well positioned, but often *uniquely* positioned to support needs in all three areas. In particular, the key partnerships and linkages being established will be extremely helpful. That said, a number of specific suggestions for each area are noted below:

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Computational toxicology:

- 1) Many new tools are already being generated by the CSS program. However, the plan says little about both the intended transparency of the process and the approach that will be used to “qualify” (i.e., validate is a term used in other circles, but was thought to be less appropriate in this case) these new tools for their intended purposes. The transparency and qualification processes are critical in order to win the confidence of a multitude of stakeholders within and external to the Agency, many of whom are not at all comfortable with these radically new and different methods. Therefore, it is recommended that the Plan describe its proposed approach for transparency and qualification of new tools and that this proposed approach be presented for review by the BOSC.
- 2) The CSS program is leading a transition from descriptive, effects-based safety assessment schemes to new testing paradigms that predict toxicity based on evaluation of cellular/molecular control pathways. Essentially these pathways are homeostatic control circuits that allow organisms to cope with a constantly changing environment. Adverse outcomes generally result only when the capacity of these homeostatic control systems is breached. Further, many pathways can produce different phenotypic outcomes depending on the context in which they are activated. Therefore, in order to interpret data from toxicity pathway-based assessments, there is a fundamental need define the normal range of intra- and inter-individual variation in these pathways, understand the context in which these pathways are activated, and distinguish changes that are adaptive vs. those that overwhelm homeostasis leading to adverse outcomes. This should involve both experimental and computational efforts.
- 3) The new computational toxicology tools being developed by the CSS program will most likely be inserted as components of larger, tiered testing frameworks, with high throughput methods comprising initial tiers, followed by more targeted testing, typically in animal models. It is suggested that the Plan address how the computational toxicology program will dovetail with higher tier targeted testing, describing how targeted testing in animals can fill critical gaps and current limitations of computational methods (e.g., complex cell and organ level interactions, toxicokinetics and determination of dose to the target site). EPA is uniquely positioned to accomplish this integration of computational methods with targeted testing by virtue of two of its world renowned laboratories located in close proximity to one another: the National Center for Computational Toxicology and the National Health and Environmental Effects Research Laboratory, both on the RTP campus. It is also suggested the CSS program work with the National Toxicology Program (also on the same campus) to suggest types of data that could be generated by NTP in order to strengthen bridges between animal-based and computational safety assessment methods.
- 4) We strongly encourage the computational toxicology program to place greater emphasis on toxicokinetics (absorption, distribution, metabolism and elimination) and physiologically-based pharmacokinetic models as these factors are major determinants of toxicity. Some effort has been made in the CSS program towards developing and applying higher-throughput methods for measuring parent chemical metabolic clearance and plasma protein binding, but additional effort (both experimental and computational) need to be made towards estimating volume of

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distribution/partition coefficients, renal excretion, bioavailability, and what metabolites are generated. Incorporation of these determinants is central to the determination of risk. In the absence of toxicokinetic understanding, risks will be both over- and underestimated for large numbers of chemicals.

Nanotechnology

- 1) Related to the theme of inherency, it is suggested that the Plan clarify whether nanomaterials will be compared to the bulk form of the chemical, as well as to environmental transformation products.
- 2) Clarification as to whether the CSS program will have the appropriate models (e.g., in vivo models, fate and transport models) should also be included.
- 3) Because nanotechnology is such a large field, EPA's unique roles and anticipated contributions vs those of other research organizations should be clearly articulated. In other words, please specify the CSS program's niche in the larger world of nanotechnology research.

Endocrine

- 1) The CSS program's research to support a transition from the current Endocrine Disruptors Screening Program (EDSP), which is extremely cost-, time- and animal-intensive, to an "EDSP21" that relies more heavily on higher throughput methods, is strongly encouraged. We recognize the many challenges in trying to shift from animal-based to high throughput endocrine screening methods, but believe that it is important that these issues be tackled head on in an objective manner. In the context of the larger movement toward toxicity pathways-based testing, the current suite of pathways falling under the umbrella of the current EDSP program are actually fairly limited (i.e., estrogen, androgen and thyroid). There are numerous other toxicity pathways constituting the complete waterfront of pathways that warrant evaluation in a comprehensive, high throughput screening program. Therefore, the knowledge gained toward transitioning endocrine screening from its current form to an EDSP21 version will undoubtedly inform similar efforts with other toxicity pathways, and thus support efforts to create an entirely new paradigm of safety assessment.

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Exposure research

How well has the exposure component of the CSS research program progressed since its inception?

Response to this charge question was addressed earlier under the question related to "research activities planned for FY 13 in section 4.2.1.

4.2.3. Major recommendations for the CSS program

General

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- Clearly demonstrate how CSS research impacts upon end users (e.g., risk managers, policy makers) and how it brings value for informing decisions.
- Increase focus on the refinement and validation of proximal and consumer exposure models, which include both external and internal dosimetry.

Computational Toxicology

- Clearly and transparently describe the proposed approach for qualification of new computational toxicology tools for their intended purpose, and present to BOSC for review.
- Define the normal range of intra- and inter-individual variation in biological control pathways in order to distinguish between adaptive vs. adverse changes.
- Address how the program will dovetail with higher tier targeted testing.
- Place greater emphasis on integration of toxicokinetics (ADME) and physiologically-based pharmacokinetic models.

Nanomaterials

- Define EPA's unique niche within the broader landscape of nanotechnology research.

Endocrine

- In the effort to transition toward EDSP21, place greater attention on the challenges involved in using reductionist approaches (e.g. ToxCast) in evaluating highly integrated physiological networks, such as the endocrine system.
- Frame the research on EDSP21 as a precedent for addressing analogous challenges for evaluating other complex integrated biological systems (e.g., nervous system).

4.3. Human Health Risk Assessment

These general comments supplement the answers to the charge questions; they address issues that extend beyond the specific charge questions provided by the EPA. They cover interactions among the four themes of the HHRA and of the HHRA across the set of research programs.

Consideration should be given to the critical place of risk assessment in the activities of EPA in the context of its placement in various research programs. The vision as currently articulated in the SARP is: "The Agency will generate timely, credible human health risk assessments to support all priority Agency risk management decisions, thereby enabling the Agency to better predict and prevent risk." Thus, risk assessment represents a methodological foundation for activities of the research programs and it cannot be placed in a siloed fashion into a single SARP. Various reports, from the EPA, the National Research Council, and other bodies, have urged improvements to approaches to risk assessment. The EPA has already made significant steps towards implementing some of those recommended improvements, but a more cohesive approach to risk assessment could be taken across the six research areas. Figure 4, describing the interrelationships among the six programs, does not adequately capture the underpinning and broad translational role of risk assessment within EPA.

Across the six programs, risk assessment figures to varying degrees. Within CSS and HHRA, risk assessment methods are mentioned extensively. While cross-program integration is proposed, the relevant agendas within these two programs are largely separated and the basis for selecting outputs and

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1 giving them priority is not clear. Even within HHRA, there is not adequate connection and synergy. For
2 example, transparent evidence synthesis is integral to both the IRIS Program and the development of the
3 ISAs, but this connection is not made. The SAB and BOSC recommend that ORD revise the CSS and
4 HHRA documents so that they more clearly communicate the inter-related science and research
5 priorities for these two programs.
6

7 Two of the themes of the HHRA have requirements for timely production of documents: the IRIS
8 Assessments and the Integrated Science Assessments (ISAs) for the National Ambient Air Quality
9 Standards (NAAQS). Some activities of Theme 3 may also have requirements for timely delivery. Thus,
10 for the HHRA, there is an inherent tension and competition between the need to produce these various
11 assessments in a timely fashion and to incorporate strategies based in “new and emerging” science into
12 its activities. This inherent tension needs to be explicitly acknowledged and considered as priorities are
13 set. Leadership will need to assure that there is consistent emphasis on consideration of the suite of
14 emerging methods, even as the priorities of production of assessments and other activities are met.
15

16 The present plan provides a straightforward description of activities within the four themes, but neither
17 provides a strong overall vision nor identifies points for synergism across the four components. At this
18 point, the four themes have certain commonalities and their merger into a single program is reflective of
19 these cross-cutting elements, particularly the reliance on the quantitative methods of risk assessment. In
20 discussions during the meeting of the SAB, Dr. Olden and his team fully recognized that integration is
21 needed and that synergies can be achieved. These limitations of the current plan are well recognized and
22 will be addressed by Dr. Olden and his team. [

Commented [E14]: AN comment –SAB reports do not include ad hominem references – can this be phrased another way?

23
24 The EPA and the staff of the HHRA have substantial expertise in the methods of risk assessment and
25 their application. With an extensive portfolio of risk assessment activities, the HHRA provides a superb
26 platform for carrying out applied research and we urge the leadership of the HHRA to pro-actively
27 utilize this opportunity to advance the risk sciences. An agenda of research should be maintained that
28 builds strategically on this opportunity and attention given to assuring that such methodological research
29 is not set aside.
30

31 The present document focuses on technical elements of the four themes, but gives insufficient attention
32 to sustainability, which is inherently within the scope of HHRA. Sustainability receives little explicit
33 mention with the Strategic Research Action Plan and the connections of the HHRA to sustainability
34 need to be embedded within the plan.
35

36 The activities of the HHRA have wide reach and will benefit from engaging a broad range of
37 collaborators. The HHRA should assure that its network of collaborations in risk assessment reaches as
38 far as possible within EPA and also extends to incorporate partners outside the agency, whether in
39 government, academia, or other sectors.
40

41 The EPA needs to assure that its staff incorporates the latest developments in risk assessment into their
42 work. Additionally, the Agency should provide training to its new employees, making certain that
43 capacity in risk assessment is optimized. A plan is needed for training in risk assessment that reaches to

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new scientists and practitioners in the agency, that keeps the staff at the “cutting edge”, and that educates decision-makers, keeping them abreast of the newest approaches.

EPA should carefully examine the placement of the risk sciences within the Agency to assure that there is sufficient integration and connection among risk scientists. Are the risk scientists sufficiently connected? The Risk Forum provides a platform for discussing specific issues, but perhaps a venue is needed for broader discussion and collaboration.

4.3.1. Overview questions

First year progress

How are the ORD research programs progressing in the first year of implementation? Are the research activities planned for FY 13 and future years appropriate for answering the science questions in the Strategic Research Action Plan?

The ORD research programs appear to be progressing very well in the first year of implementation. However, the SAB and BOSC noted that it is rather early to evaluate the trajectory of progress, and that much remains to be done in the coming years. There is an inherent tension and competition within the program between the need to produce various assessments in a timely fashion and to incorporate strategies based in “new and emerging” science into its activities. ORD should explicitly acknowledge this inherent tension and consider it in setting benchmarks for the program.

The Strategic Research Action Plan provides a straightforward description of activities within four themes (Theme 1: Integrated Risk Information System (IRIS) health hazard and dose response assessments; Theme 2: Integrated Science Assessments (ISAs) of criteria air pollutants; Theme 3: Community Risk and Technical Support for exposure and health assessments; and Theme 4: Modernizing Risk Assessment Methods). The research activities planned for FY 13 and future years seem appropriate for answering the science questions in the Strategic Research Action Plan. There are potential challenges that may interfere with the planned agenda over the longer-term. One is the already mentioned trade-off between the demands of producing timely assessment while assuring that methodological research continues. In addition, resource limitations and recent unfunded mandates placed on ORD may constrain efforts to carry out this ambitious set of research activities. Decisions about what to prioritize and what to omit will be challenging, and should be made only after the overall vision has been further developed.

Considering the linkage between the HHRA program and decision making, it is important not to overlook the importance of the exposure sciences, which are not sufficiently reflected in the SARP. The upcoming report from the National Research Council on the exposure sciences is likely to increase attention to this area and provide prioritized research needs. The discussion of exposure sciences should be expanded beyond the brief discussion in Theme 3 (Community Risk and Technical Support) in the plan. All HHRA assessments will benefit substantially from state-of-the-art exposure data and methods. The HHRA program will also benefit from enhanced ties to the ecological risk assessment community.

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Sustainability

*How are ORD programs contributing to sustainability through their research plans and activities?
What advice do the SAB and BOSC have for each research program about advancing sustainability in future research?*

The HHRA SARP did not contain any specific mention of sustainability, yet this apparent omission does not reflect omission of sustainability from the program's actual mission. The contributions made by the HHRA program in advancing the science underlying the NAAQS have driven major air quality improvements nationwide that further sustainability goals. Similarly, the role of the HHRA program in producing high-quality risk assessments (in the IRIS program) and rapid risk assessments (PPRTVs) contributes to the goal of identifying and controlling health risks from toxic chemicals and developing new tools to predict chemical risk and to further green chemistry. Finally, efforts to develop and improve the ability to identify and measure cumulative risks can help advance environmental justice and community sustainability.

The SAB and BOSC recommend that the HHRA program more clearly and explicitly communicate its significant contributions to sustainability. Furthermore, the HHRA program's efforts to train risk assessors in state-of-the-art methods and approaches through the Risk Assessment Training and Experience (RATE) program, which provides comprehensive risk assessment guidance and training, will ensure contributions to sustainability.

Balancing immediate program needs and emerging issues.

As we consider science for the future, while budgets continue to shrink, how should ORD balance its commitments in the Strategic Research Action Plan with the need to advance science on emerging issues?

EPA will need to think and act creatively to deal with the likelihood of reduced budgets, while at the same time addressing requests for assistance from various programs and from an increasingly informed public. In addition, the release of the three groundbreaking National Research Council reports (Tox 21, Science & Decisions, and Phthalates) provides an agenda and an impetus for EPA to transform its overall approach to risk assessment. This transformation needs to occur in parallel with the ongoing production of individual risk assessments, since there is a continuing need to provide the most credible possible risk numbers for decision makers. A significant amount of ORD effort should shift toward building capacity to incorporate the new toxicology data into a new risk assessment approach.

In addition to more careful coordination and priority setting with the CSS program, EPA has several other options for leveraging available resources. For example, EPA might consider the development of cooperative agreements with outside parties via the Federal Technology Transfer Act (FTTA). This act specifically allows for external funding to be put into the agency in the pursuit of technology developed by EPA, such as that developed on emerging issues and/or issues related to sustainability. EPA might also link more directly with other federal agencies, such as the Agency for Toxic Substances and Disease Registry (ATSDR), which has a similar mission for hazard identification and dose-response assessment. For example, EPA might consider jointly developing PPRVTs and Minimal Risk Levels

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with ATSDR. Moreover, if EPA has found its current collaboration around toxicity assessment with California to be helpful, EPA could partner with other outside parties, such as the State of Minnesota, NSF International, or even other governments that also conduct similar hazard identification and dose-response assessment work. Of course, NCEA would be well served to work even more closely with existing groups within the Agency, such as EPA's Office of Water or its Office of Pesticides Program for developing dose-response assessment values. For example, adding recent Office of Pesticides Program risk assessment values, or updating older pesticide values, would be a valuable addition/update to IRIS.

EPA could also respond to this likelihood of reduced budgets by addressing emerging problems through the use of newer tools, such as high throughput assays, that have the promise of high-quality and abundant data at reasonable cost. This approach would have the advantage of early use and demonstration of these emerging tools and early feedback would serve to improve their utility, efficacy, and acceptance. Another advantage in the use of these emerging tools is that they would likely expedite the overall assessment.

In addition, EPA might consider active partnerships with other entities in order to build opportunities to use high throughput testing and new observational epidemiology studies based in established cohorts. There are several advantages of this approach including the reduced use of experimental animals, the direct use of human studies, and the ready application of high throughput testing.

Furthermore, EPA should consider producing screening risk levels for chemicals, similar to the established Thresholds of Toxicology Concern (TTC) or the developing concept of Conditional Toxicity Value (CTP). The TTC approach is well established for food contaminants and is being actively studied for applicability to other environmental media. The CTP is more innovative in that it incorporates consideration of new toxicity testing methods. Both approaches would support the establishment of interim risk values for many chemicals of concern. Their processes would then allow interested stakeholders, such as industry and academia, to bring forward data and methods that will lead to more refined risk values based on chemical-specific data. If EPA decides to take this approach, then linkages with external groups with resurgent interest in these methods will be essential. Finally, EPA should incorporate consideration of shorter-term testing to improve the basis of its risk assessments, as long as time lines for the risk assessment are not unduly lengthy, and the delay is not associated with remediable, ongoing human exposures and potentially significant human health or ecological risk. EPA's NCEA should also incorporate a process to prioritize themes 3 and 4 of its HHRT given the possibility of limited resources.

Integration

Based on the presentation of five integrated topics, what advice can the SAB and BOSC provide to help ORD succeed in integrating research across the ORD programs? How can different approaches to integration help us achieve our research goals?

Much of the work of HHRA focuses upon mandated activity and is highly task-oriented. Because of the large amount of mandated work and because HHRA outputs (e.g. IRIS) provide the hazard identification

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and dose-response assessment basis, in part, for the regulatory and advisory work of EPA, integration efforts should be prioritized carefully so as not impose unnecessary burdens (undue time and effort) detracting from core activities.

Nevertheless there were a number of research topics identified for which there is high need or potential for integration/collaboration between HHRA and the other programs. SAB and BOSC recommend that cross-program collaboration between CSS and HHRA be emphasized more strongly in the Strategic Research Action Plans for the two programs. While cross- program integration is proposed, the relevant agendas within these two programs are largely separated and the basis for selecting outputs and priority setting is not clear. Even within HHRA, there is not adequate connection and synergy, as noted in the general comments.

The areas of children's health and of the health and exposures of other sensitive and vulnerable subgroups require a high level of integration across all ORD research programs. The HHRA strategic research action plan should identify key gaps between research outputs and assessment needs so that ORD can focus research to address the needed integrative models including exposure assessment, computational toxicity, developmental toxicity, in vivo effects, animal data, mechanistic models and pathway analysis. The HHRA activities can provide multiple reference doses specifically, including short-term duration doses suitable for evaluating windows of vulnerability to high exposure. HHRA assessments should also identify populations that may face greater risks due to genetic or other factors and quantify these risks, using the new possibilities afforded by advances in genetics and exposure assessment. There is need for integration of HHRA into various rapid risk assessment processes (e.g., in conjunction with Homeland Security), when there are needs for assessment of chemo-toxicity of short-term exposures and for the development of Provisional Advisory Levels (PALs). HHRA would also benefit from interaction with EPA's Office of Toxic Substances, and specifically in its development of Acute Exposure Guideline Levels (AEGLs).

ORD should monitor for topics that are candidates for integrated efforts and ORD should have approaches in place for initiating integrative activities and giving them appropriate priority. Very importantly, when new issues requiring integration arise within HHRA all programs should be notified, since there may be interests in the same topics from researchers in other ORD research program. Additionally, HHRA, as for other programs, would benefit from the integration of social, behavioral, and decision scientists into the activities related to risk assessment methodology in support of decision-making. This recommendation from the prior review remains relevant. *Innovation*
How can ORD's initial innovation activities be improved to ensure continued and long term benefits for EPA? Are there useful experiences and lessons from other research organizations about managing innovation? What guidance can the SAB and BOSC provide for ORD in developing metrics that would be most effective in assessing the success of our innovation efforts?

Innovation

How can ORD's initial innovation activities be improved to ensure continued and long term benefits for EPA? Are there useful experiences and lessons from other research organizations about

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managing innovation? What guidance can the SAB and BOSC provide for ORD in developing metrics that would be most effective in assessing the success of our innovation efforts?

Beyond the findings and recommendations provided in section 3.5 above, there are opportunities for innovation to help “reinvent” the IRIS program by doing the following: 1) substantially shortening and streamlining the documents to make them easier to use and to review; 2) incorporating Tox21 data, initially in qualitative discussions, then in parallel with traditional toxicology data, and ultimately, as appropriate, as part of critical pathway-based extrapolations; and 3) incorporating the key recent recommendations from the National Research Council Science and Decisions report on reforming risk assessment, with a particular focus on grappling with cumulative risk, making implicit default assumptions more explicit, improving characterization of uncertainty, and not assuming that the dose-response for all non-carcinogens includes a threshold. These points are all reflected in the HHRA SARP, but not as clearly as they could be.

4.3.2. Program –specific questions

Modernizing methods

What aspects of the hazard and dose-response assessments produced by the HHRA research program are most likely to benefit from the application of state-of-the-art data streams and methods (e.g., in vitro toxicity testing results, gene expression profiling data, bioinformatics and QSAR modeling)? Additionally, what approaches can be envisioned to enhance risk managers’ understanding, use and acceptance of these new methods?

This charge question has two parts. In regard to the first part, the SAB and BOSC recommend four key steps to enhance risk manager’s understanding, use, and acceptance of the new data and methods that are being developed for implementation by HHRA (data such as high-throughput studies and methods such as recommendations from the National Research Council report *Science and Decisions*). The key steps include consistent adoption of new approaches across programs, training and education, immediate implementation of new methods, and evaluating the incorporation of new methods into decision-making.

New methods or approaches are considered widely acceptable when well respected and influential risk assessment programs, including those outside of ORD and those in other agencies, incorporate new approaches in a consistent manner. New approaches and new data will gain greater acceptance by risk assessors and managers if ORD works with multiple EPA programs and other agencies to gain consensus on the use of data and methods. Consensus on each risk assessment is not needed [e.g., the Minimum Risk Levels (MRLs) produced by ATSDR need not match the IRIS reference doses (RfDs) produced by EPA], but consensus should be achieved on recommended methods, approaches, and to the extent possible, application (e.g., BMDL methodology is now widely accepted although different groups may calculate a different value). Agreement within the risk assessment community on the utility of the new approaches will enhance their credibility with risk managers.

EPA should provide training and education tailored to the information needs and backgrounds of the agency risk managers as well as those outside the agency (risk assessors, risk managers, academia, and science advisors to the communities affected by risk management decisions). The HHRA program has

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1 already given this problem careful consideration by meeting with agency risk managers in a focus group
2 venue to learn how risk managers 'receive' information about risk assessments. ORD has also described
3 the Risk Assessment Training and Experience (RATE) program and an outcome for training (FY15).
4 ORD staff already influence peer scientists through offering, planning, and participating in symposia,
5 workshops, and continuing education offerings at professional meeting. ORD is also hosting webinars
6 and other remote learning opportunities. Many of these current activities are aimed not only at NCEA
7 scientists, but also peer scientists.

8
9 While these ORD efforts are laudable, education efforts targeted to risk assessors and managers are
10 needed immediately and should be offered frequently in order to ensure that the understanding and
11 acceptance by potential users evolves along with the work that is produced. An added advantage is that
12 early training will provide ORD with timely feedback from stakeholders who may be struggling to
13 implement new approaches. Suggestions for training include:

- 14 • Sustaining the development of risk assessment methods and their implementation into
15 practice.
- 16 • Targeting innovators and influencers in various sectors (e.g., regional offices, state risk
17 assessment programs, academia, science advisors from the non-profit sector, community
18 leaders) for specific training;
- 19 • Optimizing training to match the background, experiences, and needs of change leaders;
- 20 • Developing coursework and ensuring it is taught in influential toxicology and exposure
21 science academic training programs;
- 22 • Developing public health policy training through public health institutes;
- 23 • In-laboratory rotations targeting toxicologists and risk assessors unfamiliar with new
24 technologies; and
- 25 • Sharing information about the RATE program (course content and focus, audience, and
26 delivery) and implement it as early as possible.

27
28
29 Education and training is a resource intensive activity that requires dedicated staffing and the support of
30 management, and HHRA should be adding annual output goals in this area.

31
32 The SAB and BOSC recommend that ORD begin, as soon as possible, to implement and integrate new
33 types of data and methods into risk assessments. New methods may be used in qualitative if not
34 quantitative ways in such ORD products as PPTRVs (Provisional Peer Reviewed Toxicity Values
35 derived by EPA's Superfund programs) and IRIS reviews. The HHRA program has begun to consider
36 "omics" data (e.g., genomics, proteomics, and metabolomics) and innovations described in the *Science*
37 *and Decisions* report into IRIS and other risk assessments. ORD should continue to integrate this
38 information as quickly and effectively as possible as one way to ensure that risk assessors and risk
39 managers become familiar with new types of data and methods and recognize the utility of the new
40 information. For example, each upcoming IRIS assessment for which the chemical has undergone
41 testing under the Tox21 regime should at least present the data and incorporate it into a qualitative
42 discussion. Another example (related to recommendations from *Science and Decisions* report) is to
43 include information and results appropriate for cumulative risk for chemical groupings into an IRIS
44 assessment for a chemical (a chemical that should be grouped or considered with other chemicals).

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In regard to the variability and uncertainty that may be associated with these new methods, the SAB and BOSC recommends that HHRA incorporate new data and new approaches as they become available and characterize the uncertainty and variability associated with each research result in a transparent manner. As more data become available and methods are tested further, a component of this work should include comparing traditional and non-traditional approaches to evaluate the outcome of using new methods. The data and methods might be helpful in analyzing uncertainty as well (e.g., using the unified, linear dose-response approach for a non-cancer endpoint, or incorporating omics-based assessments of variability and vulnerability into a risk assessment).

In regard to the second part of this charge question, which pertains to risk managers' understanding, acceptance and use of these new methods, the SAB and BOSC recommend that the HHRA program systematically study, perhaps through the use of decision science, the utility of the new data sources for decision-making, and determine how evidence from new areas of investigation should be combined or presented along-side of more traditional methods of risk assessment. It is clear that risk managers need to have information presented in ways that demarcate what is known from what is not known. Risk managers need information that characterizes uncertainty in a useful way. The EPA should conduct research on how to combine results from the new lines of investigation with health risk data from "traditional" toxicity testing and epidemiology. The research should the utility of these new data sources for decision-making and not only what risk managers understand about these approaches and how they may use them. ORD should consider involving decision-scientists to study the perceived utility and acceptance of findings by risk managers.

Peer review

How can the HHRA research program efficiently obtain robust peer reviews that contribute to the scientific integrity of assessments without impacting the timely provision of documents with public health value? Additionally, can the SAB/BOSC provide advice on the appropriate overall balance of peer review of individual products versus other recommended scientific capacity-building activities?

The SAB and BOSC reflected on the difficult balance between the essential role of peer review and the need for timeliness in producing risk assessments of public health importance. In some cases, repeated rounds of demand for peer review may be driven more by external factors rather than by true deficiencies in the documents. In other cases, increasingly cumbersome, lengthy, and confusing EPA assessments have made the task of peer review more difficult than it needed to be, and have resulted in negative feedback to the Agency. The SSAB and BOSC applaud the commitments in the HHRA action plan to produce more readable, shorter and well-organized IRIS assessments, and this shift should make the peer review process somewhat easier and more efficient in the future. Overall, the SAB and BOSC strongly support the scientific integrity and quality of the HHRA risk assessments and acknowledge that EPA has been extremely responsive to peer review comments (making all changes recommended by peer reviewers for all recent IRIS assessments).

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1 The SAB and BOSC recognize that difficult decisions sometimes arise, such as when a peer review
2 recommends use of a different model or a new uncertainty analysis requiring extensive time and
3 resources to produce and that would be unlikely to significantly change or improve the final assessment.
4 In such cases, the lack of a 'referee' for the peer review process places the Agency in a difficult situation.
5 The SAB and BOSC recommend creating a new role for an independent scientist to review the peer
6 review comments and determine which should be given priority and when they have been adequately
7 addressed. This type of role currently exists for peer review of reports of the National Academy of
8 Sciences as well as for all scientific journals. In other words, there should be a transparent approach to
9 triaging comments received in peer review and giving them priority so as to assure that the most critical
10 revisions are made as efficiently as possible.

11
12 The level of peer review should be generally commensurate with the complexity and importance of the
13 document, and with the time-urgency of the assessment. For example, PPRTV-type assessments
14 appropriately undergo a lesser level of peer review than IRIS assessments, and the degree of review
15 accorded an IRIS assessment varies according to its importance. However, in a few cases, additional
16 mandated reviews have created a highly significant strain on the budget and unusual delays; there is
17 concern about how recent mandates may impair the ability of the HHRA program to achieve its goals
18 and objectives in the coming fiscal year. Budget cuts should not impair efforts to incorporate the new
19 scientific data and methods, as these new methods have the potential to ultimately help improve
20 efficiency and better protect public health by allowing screening-level assessments on many more
21 chemicals than can be addressed today.

22 The agency should have the overall goal of providing its assessments in a timely way. This goal has not
23 always been met, particularly for the IRIS assessments and the past Criteria Documents. More recently,
24 the Agency has been completing the peer review of the ISAs in a timely fashion, in part because of
25 court-ordered deadlines. Additionally, the switch from the Criteria Document to the ISA format has led
26 to more synthetic and transparent documents that can be more readily reviewed. Some of the IRIS
27 assessments that have been tardy in being completed have been overly long and found to be deficient in
28 various ways. Changes in the process used to carry out the IRIS assessments should enhance peer
29 review.

30
31 ORD appreciates that the intensity of peer review is proportional to the importance of the product.
32 Toxicology reviews, reference doses, and cancer slope factors are extremely important in programs
33 across EPA and in environmental and public health actions carried out across the country. It is possible
34 that the reforms already being implemented in the IRIS program, and that lead to greater transparency
35 and stakeholder involvement early in the review process, will result in less onerous peer reviews. EPA
36 will be able to address more concerns more directly during the review and stakeholders can target their
37 comments more effectively in a peer review.

38
39 **4.3.3. Major recommendations for the HHRA program**
40

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- The EPA should broadly examine the placement of risk assessment activities within the Agency and seek to establish connections and integration that will foster ongoing enhancement of methodology.
- The HHRA leadership needs to elaborate a strategic vision that enhances linkages among the thematic areas of the HHRA and with the other research programs.
- A widely reaching plan is needed for incorporating data from emerging technologies, e.g., “omics” and high throughput testing, into EPA risk assessment approaches and for evaluating the utility of these new types of data for decision-making.
- While progress by HHRA has been on pace during its first year, the agenda needs to be set for the longer-term with priorities given to the most critical topics for decision-making, particularly as resources may decline.
- Exposure sciences need greater emphasis within the activities of the HHRA.
- Integration of HHRA approaches with those of other EPA groups would lead to greater efficiency and harmonization of approaches.
- The addition of further social, behavioral, and decision scientists to HHRA would benefit many of its activities and enhance integration.
- Sustained efforts are needed to assure that scientists with HHRA and elsewhere in EPA and decision-makers are fully versed in the latest risk assessment approaches and the interpretation and application of their findings.
- Peer reviews of HHRA products could be made more efficient. The plans for changes in the IRIS assessments should benefit peer review. Additionally, the intensity of peer review should reflect the complexity and importance of the product. For extensive peer reviews, a process is needed to triage comments so that effort is directed at the points of criticism that are most important and that have significant implications for overall risk estimates and decision-making. A transparent process is needed for this purpose that could involve an independent referee.

4.4. Safe and Sustainable Water Resources

4.4.1. Overview questions

First year progress

How are the ORD research programs progressing in the first year of implementation? Are the research activities planned for FY 13 and future years appropriate for answering the science questions in the Strategic Research Action Plan?

SAB/BOSC finds that research activities planned for FY 13 and future years are appropriate for answering the science questions in the Safe and Sustainable Water Resources (SSWR) Strategic Research Action Plan and that EPA’s planned research activities for FY13 align appropriately with EPA’s overall research goals. SAB/BOSC agrees that EPA’s progress in implementing the SSWR research program is commendable, and appreciates EPA’s efforts to balance priorities in identifying planned activities within the plan.

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SAB/BOSC recommends that EPA develop an implementation plan that includes specific tasks and milestones. In some cases EPA has all deliverables scheduled for the completion of a task, with dates as far forward as 2017 in some cases. This makes it difficult to assess the rate of progress that EPA is making towards completion of the task. While SAB/BOSC understands that an implementation plan is in development, EPA should consider including a more detailed timeline with deliverables for planned activities with specific milestones and/or intermediate deliverables. This would assist reviewers in better understanding the anticipated rate of EPA's progress towards achieving its longer-term goals and plans.

Sustainability

*How are ORD programs contributing to sustainability through their research plans and activities?
What advice does the SAB and BOSC have for each research program about advancing sustainability in future research?*

SAB/BOSC finds that EPA's SSWR Strategic Research Action Plan appropriately incorporates sustainability into EPA's research plans and agrees that EPA has greatly improved how it brings sustainability into its long-term research planning. Sustainability is a far reaching goal, and much of the progress towards achieving a sustainable society lies outside of EPA's purview. SAB/BOSC recommends that EPA further clarify what is the agency's focus vs. the focus of other agencies regarding SSWR sustainability-related research. SAB/BOSC stresses that partnering and leveraging efforts and activities of others is critically important.

Balancing immediate program needs and emerging issues.

As we consider science for the future, while budgets continue to shrink, how should ORD balance its commitments in the Strategic Research Action Plan with the need to advance science on emerging issues?.

SAB/BOSC finds that there are a number of immediate, basic SSWR research needs, such as in the areas of storm water management, microbial contamination of coastal waters, and aging water and wastewater infrastructure. As research budgets are reduced, research toward these immediate research needs will necessarily take a larger portion of EPA's SSWR research budget. Many states have a tight budget for protection of water quality, and rely heavily on EPA for research outputs on SSWR high-priority topics. Shrinking budgets will make it more difficult to prioritize research on emerging water quality issues. Prioritization of emerging issues will be needed. SAB/BOSC recognizes it will sometimes be difficult to separate basic, immediate research needs from emerging research needs – nevertheless this needs to be done. EPA has demonstrated it has the flexibility and capability to make necessary changes in research plans from year to year. SAB/BOSC encourages EPA to develop a structured way (e.g., a risk portfolio analysis) to assess relative priority of emerging issues and to reassess 'existing' emerging issues in establishing priorities.

SAB/BOSC notes that some stakeholder communities and groups will favor prioritization of SSWR research that differs from EPA priorities. SAB/BOSC recommends that EPA consider the magnitude and distribution of risks associated with not pursuing emerging SSWR research issues that could benefit

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certain communities such as environmental justice communities. SAB/BOSC also recommends that EPA transparently communicate its efforts to prioritize research, and engage with communities and conduct outreach when developing SSWR research priorities. SAB/BOSC also concludes that partnering with other federal agencies would help leverage shrinking research dollars..

Integration

Based on the presentation of five integrated topics, what advice can the SAB and BOSC provide to help ORD succeed in integrating research across the ORD programs? How can different approaches to integration help us achieve our research goals?.

SAB/BOSC encourages EPA to enhance its internal and external communication between research programs and provide more opportunities for formal exchange of research information. EPA currently provides opportunities for communication between research programs through its monthly SWAQ (Subcommittee on Water Availability and Quality) teleconference calls that discuss current agency research, and its periodic half-day meetings of ORD National Program Directors to discuss research and budget priorities. SAB/BOSC recommends that ORD identify and assess the adequacy of existing formal mechanisms for sharing research information internally and among agencies (e.g., DOE, NOAA, USGS, USDA, and others), identify barriers associated with such mechanisms (e.g., culture differences between agencies, lack of an inventory of federal environmental research), and take leadership in improving and developing new mechanisms where appropriate.

4.4.2. Program –specific questions

Nitrogen research gaps

ORD has integrated programmatic research, with EPA Program Office input, to begin developing a strategic nutrient management plan for the nation with the intent of accomplishing the SAB's recommended goal to reduce reactive nitrogen by 25 percent. Are there research gaps that would impede accomplishing this goal? (for example, should we be looking at green infrastructure for removing nutrients as well as for controlling storm water?)

SAB/BOSC identified several potential gaps in EPA's nutrient research plan. EPA should invest more in assessing use of market mechanisms for nutrient control, i.e., "nutrient trading," including evaluation of programs that have been initiated in the U.S. and elsewhere. EPA should also identify metrics for nutrient management, which will govern the direction of actions by EPA and other federal agencies, state agencies, companies, NGOs, and individuals (e.g., metrics that consider financial impacts vs. amount of N released). EPA should be engaged with and knowledgeable about research on mechanisms and forms of nutrient delivery in agriculture. Application of fertilizers consisting of highly soluble nitrogen-bearing salts is at the core of much of the nitrogen management problem. EPA should not necessarily be conducting much research itself in nutrient delivery, but should be engaged with those doing such research and motivating advances in this research.

SAB/BOSC also concludes that EPA should identify and seek opportunities for leveraging limited research dollars and manpower with other federal agencies, and utilize EPA's strengths in areas such as

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monitoring, data analysis, and modeling within such leveraged efforts. A few potentially significant leveraging opportunities include the U.S. Department of Agriculture's (USDA) Natural Resource Conservation Service (NRCS) Mississippi River Basin Initiative; the Chesapeake Bay Program's modeling, monitoring, and trading activities; the National Science Foundation's (NSF) recent, multi-nation initiative, *Nitrogen: Improving on Nature* (http://www.nsf.gov/funding/pgm_summ.jsp?pims_id=504773); and with private industry. In addition, SAB/BOSC identified several opportunities for innovation, including mechanisms and forms of nutrient delivery and improvements in nitrogen monitoring instrumentation. Innovative improvements in monitoring toward more robust, less expensive, and portable instruments would be of great value to the EPA Office of Water, USGS, state agencies, and others, and could be achieved in partnership with the private sector and universities, e.g., through open innovation competitions, and the SBIR program. To encourage innovation, SAB/BOSC recommends that EPA leverage efforts of others, conduct outreach and broadly engage the public (e.g., universities, USGS, companies, and communities), and conduct competitions that solicit innovative approaches in target areas.

Natural Infrastructure

To better accomplish our goal of using a variety of approaches to address stormwater issues, should EPA also consider incorporating natural infrastructure into research on constructed green and gray infrastructure?

SAB/BOSC concludes that EPA should incorporate natural infrastructure into its infrastructure research, and take a leadership role in conducting green infrastructure research. SAB/BOSC recommends that EPA inventory best practices and innovation activities across the U.S. to identify who's doing what now in green infrastructure. The EPA engagement with and support of the storm water research initiatives of the Water Environment Research Foundation (WERF) is appropriate and commendable, but EPA should do more to be recognized as a leader in storm water research. In addition to WERF, there are opportunities for EPA to partner with the USDA, the Environmental and Water Resources Institute of ASCE, architectural, engineering, and landscape architectural companies and associations, universities, StormCon organizers (an annual professional conference; <http://www.stormcon.com/>), and other organizations to assess lessons learned on this topic. Innovative solutions in storm water management are being developed in cities such as Chicago, Philadelphia, and Atlanta. Some communities have struck out on their own to investigate innovative options for storm water retention in urban watersheds, since technical leadership from EPA on this topic is limited. Much can be learned from these activities. SAB/BOSC encourages EPA to develop tools to encourage (and improve) how states help communities address Combined Sewer Overflow consent order requirements in innovative ways. SAB/BOSC also recommends that EPA examine the National Research Council's 2008 report on "Urban StormWater Management in the United States" (<http://www.nap.edu/catalog/12465.html>) which provides a series of recommendations for regulation and research needs on storm water monitoring and modeling. EPA should also support competitions that solicit innovation in these areas..

4.4.3. Major recommendations for the SSWR program

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- EPA should develop an implementation plan that includes specific tasks and milestones, and include that plan in ORD's SSWR Strategic Research Action Plan.
- SAB/BOSC recommends that EPA further clarify what is the agency's focus vs. the focus of other agencies regarding SSWR sustainability-related research.
- As research budgets are reduced, research toward immediate, basic SSWR research needs will necessarily take a larger portion of EPA's SSWR research budget.
- EPA should develop a structured way to assess emerging issues in establishing priorities for SSWR research.
- EPA should consider the magnitude and distribution of risks associated with not pursuing emerging SSWR research issues that could benefit certain communities such as environmental justice communities.
- EPA should transparently communicate its efforts to prioritize research, and engage with communities and conduct outreach when developing SSWR research priorities.
- EPA should invest more in assessing use of market mechanisms for nutrient control, and identify metrics for nutrient management.
- EPA should be engaged with and knowledgeable about research on mechanisms and forms of nutrient delivery in agriculture.
- EPA should identify and seek opportunities for leveraging research with other federal agencies, and utilize EPA's strengths in areas such as monitoring, data analysis, and modeling within such leveraged efforts.
- EPA should assess and encourage opportunities for innovation in nutrient research.
- EPA should take a leadership role in conducting green infrastructure research, and incorporate natural infrastructure into its SSWR research.
- EPA should inventory best practices and innovation activities, and seek partnership opportunities to assess lessons learned related to green infrastructure.
- EPA should develop tools to encourage/improve how states help communities address Combined Sewer Overflow consent order requirements.
- EPA should support competitions that solicit innovation in storm water monitoring and modeling.

4.5. Homeland Security

4.5.1. Heading Level 3

4.5.2. Overview questions

First year progress

How are the ORD research programs progressing in the first year of implementation? Are the research activities planned for FY 13 and future years appropriate for answering the science questions in the Strategic Research Action Plan?

Normal paragraph text that is TNR 12 point, left justified, no indents, one line between paragraphs.

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Sustainability

*How are ORD programs contributing to sustainability through their research plans and activities?
What advice does the SAB and BOSC have for each research program about advancing sustainability in future research?*

Normal paragraph text that is TNR 12 point, left justified, no indents, one line between paragraphs.

Heading Level

Balancing immediate program needs and emerging issues.

As we consider science for the future, while budgets continue to shrink, how should ORD balance its commitments in the Strategic Research Action Plan with the need to advance science on emerging issues?.

Normal paragraph text that is TNR 12 point, left justified, no indents, one line between paragraphs.

Integration

Based on the presentation of five integrated topics, what advice can the SAB and BOSC provide to help ORD succeed in integrating research across the ORD programs? How can different approaches to integration help us achieve our research goals?.

Normal paragraph text that is TNR 12 point, left justified, no indents, one line between paragraphs.

Innovation

How can ORD's initial innovation activities be improved to ensure continued and long term benefits for EPA? Are there useful experiences and lessons from other research organizations about managing innovation? What guidance can the SAB and BOSC provide for ORD in developing metrics that would be most effective in assessing the success of our innovation efforts?

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4.5.3. Program –specific questions

First program specific question title

Program Specific Question

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Second Program Specific Question Title

Text of Program-specific question

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4.6. Sustainable and Healthy Communities

4.6.1. Overview questions

First year progress

*How are the ORD research programs progressing in the first year of implementation? Are the
research activities planned for FY 13 and future years appropriate for answering the science
questions in the Strategic Research Action Plan?*

The SAB recognizes that developing and implementing the Strategic Research Action Plan for such a
visionary program is not an easy task and requires major shifts in research direction and culture. The
SAB applauds what the SHC program has accomplished so far. Overall, the first three themes have
made the most progress. The fourth theme will require more time, effort, and—importantly—focus to
fully develop. Overall, the SAB thinks the SHC program is on the right track.

Integrating ecological and human health. In particular, the SAB commends the program for bringing
together human health and ecological services and recognizing it as a priority area. Although this
integration requires considerable effort, it is an important area that is worthy of investment. Moreover,
EPA is the one agency that is positioned to do this. There was some concern that the communication
flow among the different layers of expertise (e.g., ecosystems, human health) was not at the level
needed. The SAB recognized that communication and interaction are being attempted. The SAB
encourages sustained efforts to promote interaction. The Agency should outline the barriers to this
integration and think creatively about strategies that might help to overcome them.

Challenges to integrating ecological & human health include:

- Measuring human health at the community scale. Privacy laws make it difficult to obtain fine-
scale human health/safety data, which is often needed to link to ecosystem services. ORD is
currently doing meta-analyses to try to get better fine-scale information. A current project based
in New Bedford MA is an example where they are getting fine-scale ecological and human data
- Funding, resources and time limitations
- A lack of expertise and critical mass for addressing these challenges (though webinars and
meetings are helping the agency to build capacity)
- Entrenched disciplinary mindsets that will take time and effort to overcome.

The following was recommended as a useful reference: Di Giulio, R.T. and W.H. Benson (eds.).
2002. *Interconnections Between Human Health and Ecological Integrity*. SETAC Press, Pensacola, FL.
Inclusion of social, behavioral and decision sciences. Social, behavioral and decision sciences are an
essential component of the SHC program. Social, behavioral and decision sciences contribute to
understanding human actions that drive environmental, social and economic change, the value of
ecosystem services, development of decision-support tools, the design of policies, and the behavioral
responses to policy changes. SHC has taken a step in the right direction but much work remains to be
done. The SAB was pleased with the recognition of the importance of integration and efforts to engage
social, behavioral and decision scientists. The SAB would like to see future efforts expanded.

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Distinguishing research from implementation. Throughout the action plan, it was difficult to separate (a) research from implementation and (b) client from partner from community. These lines were gray. There was concern about mission creep with SHC moving into implementation. SHC is not in a position to implement programs, both because of limited resources and because the fundamental mission of ORD is research. Implementation should be done by the regional offices, state environmental agencies, or partner communities. Implementation is of fundamental importance but the question is who should be doing it. The SAB suggests that SHC articulate a plan for interacting with local communities, state environmental agencies, and regional offices and distinguish research from implementation in the text. For example, the research and tool development conducted by ORD does support local communities, but that support is implemented through the regional offices. This might have been the intention of SHC all along, but it was not clear in the wording of the Strategic Research Action Plan .

Focusing the science questions and research. There was some concern that there were too many science questions, with most being sweeping in scope. The Strategic Research Action Plan needs to better explain how the questions will be answered. Moreover, the plan would benefit from being more sharply focused in terms of the stated research objectives, especially in light of resource constraints. Of course, the tension is, do you write a plan towards the resources one has or write a plan towards the resources you want? At the very least, the program should prioritize the science questions. The SAB recommends that initially SHC emphasize focused questions and small victories, rather than the most ambitious projects at the beginning. In other words, SHC should emphasize those projects that are tractable and can be understood well.

Engaging communities and building partnerships. The SAB commends SHC for engaging stakeholders in community listening sessions. However, more structured and guided methods will allow for a better understanding of community values, needs/wants, and constraints. There also remained some confusion about what SHC means by community engagement. The SAB suggests that SHC clarify its view of what community engagement, participatory research, and community self-assessment mean for the program. SHC can draw upon the previous work that has been done in this area. The following were suggested as useful references and provide a historical context:

Israel BA, Parker EA, Rowe Z, Salvatore A, Minkler M, et al. 2005. *Community-Based Participatory Research: Lessons Learned from the Centers for Children's Environmental Health and Disease Prevention Research*. Environmental Health Perspectives 113(10).
<http://ehp03.niehs.nih.gov/article/ehpArticle.action?articleURI=info:doi/10.1289/ehp.7675>
National Academy of Sciences. 2008. *Public Participation in Environmental Assessment and Decision Making*. Washington, DC: National Academies Press.
National Research Council. 2005. *Decision Making for the Environment: Social and Behavioral Science Research Priorities*. The National Academies Press Washington, DC.
Pasick R, Oliva G, Goldstein E, Nguyen T. 2010. *Community-Engaged Research with Community-Based Organizations: A Resource Manual for Researchers*. University of California San Francisco.
http://ctsi.ucsf.edu/files/CE/manual_for_researchers_agencies.pdf

U.S. EPA Science Advisory Board. 2001. *Improved science-based environmental stakeholder processes: An EPA Science Advisory Board commentary*.

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EPA-SAB-EC-COM-001-006. Washington, DC: EPA.

Developing a typology of communities. There was concern expressed about the typology study and that classification schemes being used to identify and classify communities; is this reinventing the wheel? Can the program use definitions already developed, for example, work done in urban planning and demography? Studying the typology of communities may not provide the information needed by the SHC program. The program's focus on decision support makes it clear that a typology of *decisions* would be a much more useful study. Having a typology of decisions and the kind of information that one needs to inform choices, across different decision making contexts or categories would be valuable. Some possibly useful references:

Frey, William H. 2007. America's New Demographics: Regions, Metros, Cities, Suburbs and Exurbs.

<http://www.brookings.edu/research/speeches/2007/02/12demographics-frey>.

Frey, William H. 2012. *Diversity Explosion : How New Racial Demographics are Remaking America*.

Brookings Institution Press.

Other issues needing attention:

- Clearly identifying the responsible party for various activities and outputs. Sometimes it wasn't clear if it was SHC or a partner that would be doing the work.
- Clarify how SHC would link with program offices and the Agency's regulatory decisions.
- Provide an idea of how many communities can/will be studied and how they are being selected. How are they prioritized? The current case study community, Durham, NC, while convenient is not necessarily representative.
- Clarify what is (and is not) meant by decision-support "tool".
- Improve alignment of science questions, activities, and outputs.
- Explicitly identify the clients and the decisions that the clients need to make.
- Aim for middle-ground models that have the right level of simplicity and synthesis.
- Given that we want to have communities at the table and engaged, the report, the language and text is written in a way that it might not be accessible to many communities.
- Does the program have a definition of sustainability that applies to communities and is more functional relative to goals of this program than the overall EPA definition? Also, where is the "future generations" piece in the definition – an emphasis on the long-term is missing.
- Better interface with decision-makers - how do models like TRIO support or aid decision-makers? What are the specific decisions that they need to make? What is the level of detail of the data that they need? Will the model provide this?
- More detail about the models is needed (e.g., what is TRIO?). There is considerable confusion about what they are and their level of complexity. Admittedly, part of this confusion stems from the fact that models and approaches are in development.

The following reference may be useful as ORD grapples with these questions/comments:

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Gregory, R., L. Failing, M. Harstone, G. Long, T. McDaniels, and D. Ohlson. 2012. Structured Decision Making: A Practical Guide to Environmental Management Choices. Wiley-Blackwell, Chichester, UK.

Commented [E15]: AN: Need to reformat

Sustainability

How are ORD programs contributing to sustainability through their research plans and activities? What advice does the SAB and BOSC have for each research program about advancing sustainability in future research?

The SHC program has integrated sustainability into its plans exceptionally well. There was some concern that there is no long-term commitment to the program and the concept of sustainability. However, the original foundation and rationale for the existence of EPA to promote human and environmental health provide a strong basis to pursue the SHC program. The SHC program brings that statement to life.

The way the problem is framed it suggested that the chief barrier to sustainability is a lack of integration among these complex systems. However, many communities can identify a wide range of specific problems other than lack of integration that present barriers. Integration is one problem but not the only problem.

Balancing immediate program needs and emerging issues.

As we consider science for the future, while budgets continue to shrink, how should ORD balance its commitments in the Strategic Research Action Plan with the need to advance science on emerging issues?.

Because SHC has a strong focus on both (a) developing useful tools and platforms and (b) identifying the best processes for developing those tools, knowledge generated in this program will be translatable across a wide range of issues and will build capacity within the program to meet unanticipated and emerging issues.

Anticipatory research is another strategy to prepare for emerging issues. Equally important is for ORD to try to understand what has contributed to slow responses in the past to emerging / important issues.

What permits the early detection of a signal before it reaches a critical state? What cultural, institutional, technical barriers were there to detecting?

Finally, emerging issues will be better identified and anticipated if staff are at the frontier of the science. Thus, it is important to build capacity in staff by providing resources to travel to meetings and interact with colleagues. Webinars, seminars, and short-courses also can help keep staff abreast of emerging issues. Many experts travel to locations with ORD staff and it may be possible to interact with these experts at low cost. In addition, there should be better use of scientific expertise outside EPA through partnerships with other agencies and with academics.

Integration

Based on the presentation of five integrated topics, what advice can the SAB and BOSC provide to help ORD succeed in integrating research across the ORD programs? How can different approaches to integration help us achieve our research goals?.

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Innovation

How can ORD's initial innovation activities be improved to ensure continued and long term benefits for EPA? Are there useful experiences and lessons from other research organizations about managing innovation? What guidance can the SAB and BOSC provide for ORD in developing metrics that would be most effective in assessing the success of our innovation efforts?

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4.6.2. Program –specific questions

Providing tools to effectively support communities

The Sustainable and Healthy Communities Research Program incorporated a number of diverse research elements (e.g., ecosystem goods and services, human health outcomes, waste and contaminant remediation, environmental indicators) in building a research program focused on supporting community decision-making. The SHC Strategic Research Action Plan aims to provide science-based research and tools to assist communities in evaluating their decisions from a sustainability perspective. What advice can the SAB/BOSC provide to help ensure this research and these tools will most effectively support communities in doing so?

There is a need to build effective partnerships with communities so that both communities and the Agency have input and contribute to the process. This process should not be driven solely by the community or by the agency, but rather be a partnership of the two that builds capacity in both. The Agency should recognize that communities may not always know what they need but that they also often have important knowledge that is difficult for those outside the community to know. To facilitate these interactions, SHC can develop a structure by which communities can engage.

The goal of tool development is not to have SHC “fix” communities but to develop processes that allow communities to make better decisions. To be of greater value, tools should be applicable for a wide range of communities. The SAB also thinks that social, behavioral and decision scientists should be part of this dialogue and play an important role in tool development.

Much useful work has been done outside the Agency on community engagement. The SAB thinks that SHC should learn more about the history of community engagement and how past practices have impacted communities. The SHC program doesn’t need to start over with new meetings in communities where people have been meeting already for a long time.

SHC should acknowledge that information alone will not ensure that communities will make more sustainable decisions. Information can sometimes help but often it is other social, behavioral, political or economic obstacles that impede progress. It would be beneficial for SHC to direct more attention to

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research that identifies how to select and use specific kinds of data to inform decisions and evaluate outcomes.

It is not always obvious how to use tools and information. SHC needs to have a plan on how to provide training and documentation to support use of tools and information developed by the program. Even the best tools and information will not be used without such support. Support tools also can provide information on how to make good choices. If the decision support tools allow people to see not only the outcome, but how good decisions are made, then communities will learn about the process of decision making and the lessons will be transferable across a variety of scales and communities.

Providing uniform, national-level data, as with the National Atlas, can be a valuable resources. Having such a resource is likely to spur new applications that may not be known at the outset. The library of ecosystem services is also an important value-added activity of the SHC program.

There is opportunity to collaborate with other programs. For example, outputs under “Enhancing Community Public Health” can be pursued collaboratively with HHRA.

SHC Theme 4

The SHC’s fourth theme investigates sustainability practices within four high priority decision sectors identified during SHC community listening sessions. These sectors are: transportation, land use, buildings and infrastructure, and waste and materials management. There are three primary goals: to assess opportunities for communities to achieve greater synergies from practices within a given sector and across multiple sectors; to provide methods to more comprehensively account for these practices in terms of their social, economic, and environmental outcomes; and to collaboratively apply and refine these findings in partnership with specific communities (e.g., Durham, NC). Does the Committee agree that this fourth theme provides a useful way to integrate research within SHC? If so, what are the most important implementation questions that ORD must address?

Commented [E16]: Insert name of Theme 4

The SAB applauds the integration that is evident in Theme 4. It is vital that tools and analysis be truly integrative across the range of social, economic and environmental realms. This theme is critical to bringing the SHC program together and, in many ways, represents the fruition of the first 3 themes.

While the group recognized that the set of four decision sectors chosen as a result of feedback from communities are important, they are not all inclusive. It was not clear in the plan that all media (i.e., air, water, and land) will be analyzed for each of the decision sectors.

In the plan, it wasn’t clear how one extrapolates from one place-based analysis to other places.

Extrapolation could occur at the level of the decision support processes and tools that are developed; however, SHC needs to explain this more clearly. There was also some concern expressed that focusing on a single site is not sufficient. There is value in choosing multiple sites with different environmental, social and economic contexts to provide comparisons. The question of how to scale up and provide nationally relevant information from particular place-based research also deserves further thought.

Emphasizing the point of case studies is to learn about process, and the lessons about process can be extrapolated and applied to other places.

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There was concern about the ability of place-based research to identify outsourcing of negative impacts. For example, a community that exports wastes may shift problems to other communities. Tools should integrate across space similar to systems approaches that integrate across sectors.

To aid in development of useful tools, the SHC program should review previous efforts at tool development. What other tool development efforts were successful and unsuccessful and why did prior programs succeed or fail. Learning from past failures is as important as learning from past successes. While it is vitally important to take an integrative systems approach, there is a real danger that such approaches can become complex and unwieldy so that they do not deliver useful results in a reasonable time frame. The more one integrates, the more complicated and less tractable the problem can become. Great care needs to be taken to focus on the really crucial interacting pieces and not get overly complicated.

SHC should be cautious not to create sector-based silos (e.g., waste, infrastructure) as they remove the disciplinary silos. There is opportunity to integrate across the decision sectors, as there are important interactions among them.

Proper balance between breadth and depth

Proper balance between breadth and depth

As a whole, the SAB thought there was good balance with about the right tradeoff between breadth and depth. That said, the plan could better highlight efforts being undertaken to understand system dynamics that include important interrelationships and the possibility of thresholds. Currently, much of the emphasis is on collecting data and developing metrics and less progress has been made on understanding system dynamics.

Data collection should be more tightly linked to the decision-support process. The SAB recommends that SHC explicitly identify the likely suite of community objectives and desired outcomes, determine what metrics one needs to measure performance or progress towards the objectives, and direct data collection efforts for those metrics.

All of the themes were seen as important, with theme 2 perhaps being the most foundational to the other themes and science questions. Were budgets to be cut, the recommendation would be to prioritize the science questions and address the most important of these rather than eliminate any theme. In this regard, it was noted that it is important to consider the architecture of the program and to be attentive to linkages among the themes. For example, there is work being undertaken in other themes that supports efforts focused on theme 2.

The SAB thinks there is much valuable research that could be accomplished if budgets were to grow. As it stands, the SHC program has set out a very ambitious plan without sufficient resources in the current budget to accomplish all of it. Expanding the budget would allow the SHC program to accomplish more of its research plan and to do so in greater depth that adds greater value.

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There is a strong need to invest more in social, behavioral and decision sciences. Decision-scientists, economists, sociologists should be integrated in a question-specific way. Individuals who study unintended consequences, which often arise because of behavioral responses, would be very useful. Ultimately, investing in these skill sets will increase the efficiency/effectiveness of SHC efforts. It also sends a strong signal to the academic community about the value of interdisciplinarity.

Investment in more communities that represent broader diversity across types would be useful.

4.6.3. Major recommendations for the SHC program

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REFERENCES

(Use “Un-Numbered Header” Style)

Reference, A. Year. Title of article in all its long, gory detail that runs on and on across multiple lines of
text. *Journal* v:p-p.

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APPENDIX A: ORD Charge to the SAB and BOSC

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